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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,456	04/06/2001	Stuart B. Levy	PKZ-030	6918

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/04/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,456

Applicant(s)

LEVY ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Amendment Entry

1. The amendment filed December 23, 2002 has been entered. Claims 1-15 and 26 have been cancelled. Claims 27-28 have been amended. Claims 16-25 and 27-28 are under consideration in the office action.

Election/Restrictions

2. Applicant's election with traverse of Group 6 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the restriction should be reformed to incorporate newly amended claims 27-28 as they are now directed towards method for identifying a compound that modulates antibiotic resistance. This is not found persuasive because despite the fact that the same preamble is recited, the method steps require additional reagents such as BLR binding polypeptides which are unlike claims 16-25. Furthermore, the he methods of claims 27 and 28 have different outcomes and effects. Thus claims 27-28 do not comprise similar method steps; furthermore, the methods require unrelated steps that require additional search and consideration and are therefore deemed to be restrictable from group 6.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
4. Acronyms like BLR must be spelled out when used for the first time in the specification.
5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
6. The use of the trademark TWEEN and other similar reagents has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 16-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 16-25 are drawn to a method for identifying compounds that modulate antibiotic resistance in a microbe comprising a contact step; determination step and selection step which thereby identify compounds that modulate antibiotic resistance. The claims are so broad that they encompass determining every modulation of activity in every type of microbe antibiotic resistance, however applicants have not described such a method. The instant specification fails to provide a method wherein every modulation of activity or expression of BLR is determined.

The specification fails to teach that every type of microbe can be used within the claimed method. There is no teaching that contacting a BLR polypeptide with a test compound will determine antibiotic resistance in a parasite, virus, fungus, yeast and all bacteria. Moreover, the art teaches that beta-lactams are antibacterials that fail to affect other microbes such as parasites. There is no written description of any method steps which teach such broadly claimed methods. There are no examples that teach by selecting compounds that modulate the activity of the BLP polypeptide, those compounds will further modulate the antibiotic resistance of any type of microbe. The claims fail to recite what medium the method occurs in. There is no requirement for the method to be *in vitro* or *in vivo*. There is no teaching of a universal microbe to be used

in the claims. There is no data showing that the unidentified compound will modulate activity in every microbe.

US Patent 5,998,159 see Watson et al., teach although the extent to which bacteria develop resistance to antibiotic drugs and the speed with which they do so vary with different types of drugs, resistance has inevitably developed to all antimicrobial drugs. There is no one drug that modulates the resistance of every type of microbe. Watson et al., further discusses different types of drugs for different types of organisms. Thus art of determining compounds that modulate antibiotic resistance is highly unpredictable in view of the growing numbers of resistant bacteria and the instant specification fails to provide any information that an unidentified compound could modulate the antibiotic resistance of any microbe solely based on the interaction of the BLR polypeptide and test compound.

The specification does not provide substantive evidence that the claimed method is capable of identifying all compounds that modulate antibiotic resistance in all microbes. This demonstration is required for the skilled artisan to be able to use the claimed method for their intended purpose of identifying compounds that modulate antibiotic resistance in a microbe.

Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the method for identifying compounds that modulate antibiotic resistance in a microbe. Furthermore, the specification fails to adequately disclose a description of the method for identifying compounds that modulate antibiotic resistance in a microbe, thus a skilled artisan would be required to de novo locate, identify and

characterize the claimed method and compound. Accordingly, this would require undue experimentation given the fact that the specification is completely lacking in teachings as to a method for identifying compounds that modulate antibiotic resistance in a microbe.

8. Claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of the claims is drawn to a method for identifying compounds that modulate antibiotic resistance in a microbe, however the recited steps within the method comprise contacting a BLR polypeptide with a test compound; followed by a determination step; and selection step. There is no correlation step which correlates the modulation of BLR activity to antibiotic resistance in a microbe. Therefore, the goal of the preamble is not commensurate with the steps of the method that are drawn to identifying compounds.

9. The term "modulates" in claim is a relative term which renders the claim indefinite. The term "modulates" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore the metes and bounds of modulates activity cannot be determined, since no specific activity is defined and no specific type of modulation is required.

10. Acronyms like BLR must be spelled out when used for the first time in a chain of claims.

11. Claim 16 recites the limitation "the activity" in the claim. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 18 recites the limitation "the cell in which it is present." There is insufficient antecedent basis for this limitation in the claim.

13. Claims 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims omit the following steps. The claims lack a positive recitation of method steps that recite a detection of the interaction between the BLR polypeptide and test compound. There are no steps which recite how to determine the modulation of BLR activity. There are no steps that incorporate the addition of necessary reagents to monitor the interaction. There are no comparison steps that compare the activity seen with and without the test compound to determine modulation. There are no identification steps that teach how to identify compounds. Finally there are no recited correlation steps that correlate the modulation of BLR activity to antibiotic resistance in a microbe.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 16-17 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Boggs et al., (US Patent 5,883,074). Boggs et al., teach methods of screening for compounds that potentiate the activity of antibacterial agents against bacteria. Beta-lactams are well known as antibacterial agents that are highly effective to treat bacterial infections (col. 1 lines 50-54). Such potentiators can reduce the Minimum Inhibitory Concentration (MIC) of an antibacterial agent which will completely inhibit growth of a susceptible strain (col. 4 lines 15-20). Potentiated antibacterial agents are beta-lactams, beta-lactam mimics, glycopeptides and the like (col. 6 lines 13-20). The potentiation screening assays determine whether or not a test compound such as unknown pharmacological, enhance the ability of the antibacterial agent to stop bacterial growth using high throughput whole cell assays (col. 11 lines 59-65). The assays combine beta-lactams and test compounds and thereby determine the MIC effect on bacteria, just as the instant claims require. Boggs et al., also teach in vitro application of potentiator assays (col. 15 lines 48-50).

It is noted that the instant specification teaches BLR polypeptides as polypeptides sharing the ability to promote drug resistance in a cell (page 6). Likewise the prior art teaches that the antibacterial activity is the ability of a compound to effect

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the inhibition of growth of the bacterium (col. 7 lines 52-56). Therefore the BLP polypeptide of the instant specification and the polypeptide of the prior art are equivalent. The prior art peptide appears to possess the same or similar functional characteristics. Since the Patent Office does not have the facilities for examining and comparing applicants' method with the method of the prior art reference, the burden is upon the applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed method of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Therefore Boggs et al., teach a method for identifying compounds that modulate antibiotic resistance.

Prior Art

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cox et al., (US Patent 5,672,497) teach methods for increasing the antibiotic producing ability of microbial host. Watson et al., (US Patent 5,998,159) teach methods for screening for antibiotics.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 

February 25, 2003


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600